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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q86357

Tetsuro KIKUCHI, et al.

Appln. No.: 10/540,577

Confirmation No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Filed: June 24, 2005

Examiner: Not Yet Assigned

For: CARBOSTYRIL DERIVATIVES AND SEROTONIN REUPTAKE INHIBITORS FOR  
TREATMENT OF MOOD DISORDERS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003. A copy of the International Search Report is also being submitted. The documents listed on Sheet 1 of the Form PTO/SB/08 are the ISR documents. The documents on Sheets 2-5 are additional documents not listed on the ISR.

INFORMATION DISCLOSURE STATEMENT

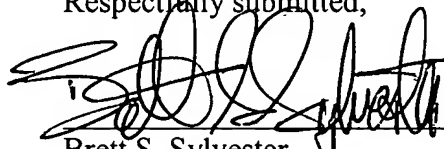
U.S. Appln. No.: 10/540,577

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The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Respectfully submitted,



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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: July 15, 2005

Substitute for Form 1449 A & B/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	10/540,577
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		First Named Inventor	Tetsuro KIKUCHI
		Art Unit	
		Examiner Name	
Sheet 1 of 5	Attorney Docket Number	Q86357	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
	1	US 2002/0156067	A1	10-24-2002	Wong, et al.

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	2	WO	02/060423	A2	08-08-2002	Otsuka Pharmaceutical Co., Ltd.	
	8	WO	2004/010932	A2	02-05-2004	Peter Migaly	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>	
	3	CINDY P. LAWLER, et al., Interactions of the Novel Antipsychotic Aripiprazole (OPC-14597) with Dopamine and Serotonin Receptor Subtypes, Neuropsychopharmacology, 1999, vol. 20, no. 6, pp. 612-627		
	4	KEVIN D. BURRIS, et al., Aripiprazole, a Novel Antipsychotic, Is a High-Affinity Partial Agonist at Human Dopamine D2 Receptors, The Journal of Pharmacology and Experimental Therapeutics, 2002, vol. 302, no. 1, pp. 381-389		
	5	GOODMAN et al., "The Pharmacological Basis of Therapeutics", 2001, vol. ed. 10, p. 451 and p. 468		
	6	SHELDON H. PRESKORN, Relating Clinical Trials to Psychiatric Practice: Part I: The Case of a 13-Year Old on Aripiprazole and Fluoxetine, Journal of Psychiatric Practice, 2003, vol. 9, no. 4, pp. 307-313		
	7	BEN GREEN, Focus on aripiprazole, Current Medical Research and Opinions, 2004, vol. 20, no. 2, pp. 207-213		

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	9	US 6,147,072		11-14-2000	Bymaster et al.
	10	US 2003/0027817		02-06-2003	Tollefson
	12	US 2002/0123490		09-05-2002	Howard, JR.
	33	US 5,958,921		09-28-1999	Tollefson
	36	US 2002/0156067		10-24-2002	Wong et al.
	37	US 2003/0109546		06-12-2003	Fenton
	39	US 5,945,416		08-31-1999	Shannon et al.
	41	US 2003/0130334		07-10-2003	Muller
	44	US 60/473,378		05-23-2003	Tetsuro Kikuchi et al.

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	11	EP	958824		11-24-1999	Eli Lilly & Co.	

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	13	ROTHSCHILD, Management of Psychotic Treatment-Resistant Depression, The Psychiatric Clinics of North America, 1996, vol. 19, no. 2, pp. 237-252	
	14	WOLFERSDORF, et al., Pharmacotherapy of Delusional Depression: Experience with Combinations of Antidepressants with the Neuroleptics Zolopine and Haloperidol, Neuropsychobiology, 1994, vol. 29, pp. 189-193	
	15	WOLFERSDORF, et al., Paroxetine as Antidepressant in Combined Antidepressant-neuroleptic Therapy in Delusional Depression: Observation of Clinical Use, Pharmacopsychiatry, 1995, vol. 28, no. 2, pp. 56-60	
	16	CZYRAK, et al., Pharmacological Effects of Zolopine and other Antipsychotics on the Central 5-HT <sub>2</sub> Receptors, Pharmacopsychiatry, 1993, vol. 26, no.2, pp. 53-58	
	17	MCELROY, et al., Clozapine in the Treatment of Psychotic Mood Disorders, Schizoaffective Disorder, and Schizophrenia, Journal of Clinical Psychiatry, 1991, vol. 52, no. 10, pp. 411-414	
	18	MELTZER, et al., Psychopharmacology, The Third Generation of Progress, 1987, pp. 1021-1029 and 1031-1049	
	19	BERNSTEIN, J.G., Induction of obesity by psychotropic drugs, Ann. NY Acad. Sci., 1987, vol. 499, pp. 203-215	
	20	BERNSTEIN, J.G., Psychotropic drug induced weight gain: mechanisms and management, Clinical Neuropharmacology, 1988, vol. 11, suppl. 1, s194-206	

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	21	JACOBSEN, Risperidone in the Treatment of Affective Illness and Obsessive-Compulsive Disorder, Journal of Clinical Psychiatry, 1995, vol. 56, no. 9, pp. 423-429	
	22	CENTORRINO, et al., Serum Levels of Clozapine and Norclozapine in Patients Treated With Selective Serotonin Reuptake Inhibitors, American Journal of Psychiatry, 1996, vol. 153, no. 6, pp. 820-822	
	23	SAXENA, et al., Risperidone Augmentation of SRI Treatment for Refractory Obsessive-Compulsive Disorder, J. Clin. Psychiatry, 1996, vol. 57, pp. 303-306	
	24	WEISLER, et al., Adjunctive Use of Olanzapine in Mood Disorders: Five Case Reports, Annals of Clinical Psychiatry, 1997, vol. 9, no. 4, pp. 259-262	
	25	O'CONNOR, Adding Risperidone to Selective Serotonin Reuptake Inhibitor Improves Chronic Depression, Journal of Clinical Psychopharmacology, 1998, vol. 18, no. 1, pp. 89-91	
	26	MARSHALL, et al., Bupropion and setraline combination treatment in refractory depression, J. Psychopharmacology, 1995, vol. 9, no. 3, pp. 284-286	

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	27	ARMSTRONG, et al., Blood Clozapine Levels Elevated by Fluvoxamine: Potential for Side Effects and Lower Clozapine Dosage, Journal of Clinical Psychiatry, 1997, vol. 58, no. 11, p. 499	
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	29	TOHEN, et al., Olanzapine versus placebo in the treatment of acute mania, Eur. Neuropsychopharmacol., 1998, vol. 8, no. suppl. 2, s178	
	30	NEMEROFF, Augmentation Strategies in Patients with Refractory Depression, Depression and Anxiety, 1996-1997, vol. 4, no. 4, pp. 169-181	
	31	NELSON, Overcoming Treatment Resistance in Depression, Journal of Clinical Psychiatry, 1998, vol. 59, suppl. 16, pp. 13-19	
	32	BODKIN, et al., Combining Serotonin Reuptake Inhibitors and Bupropion in Partial Responders to Antidepressant Monotherapy, Journal of Clinical Psychiatry, 1997, vol. 58, no. 4, pp. 137-145	

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	34	SHELTON, et al., A Novel Augmentation Strategy for Treating Resistant Major Depression, American Journal of Psychiatry, 2001, vol. 158, no. 1, pp. 131-134	
	35	CASSIDY, et al., Addition of Fluoxetine to Clozapine, American Journal of Psychiatry, 1992, vol. 149, no. 9, p. 1274	
	38	CITROME, et al., Pharmacokinetics and safety of aripiprazole and concomitant mood stabilizers, Neuropsychopharmacology, 2002, vol. 5, suppl. 1	
	40	Therapie, 1999, vol. 54, no. 2, pp. 267-269	
	42	MÖLLER, et al., Treatment of Bipolar Disorder, J. Clin. Psychiatry, 2003, vol. 64, suppl. 6, pp. 9-17	
	43	KOWATCH, et al., The Use of Mood Stabilizers and Atypical Antipsychotics in Children and Adolescents With Bipolar Disorders, CNS Spectrums, 2003, vol. 8, no. 4, pp. 273-280	
	45	WORTHINGTON, et al., Aripiprazole as an Augmentor of SSRIs in Mood and Anxiety Disorders Patients, American Psychiatric Association 2003 Annual Meeting, May 17-22, 2003 (poster, May 19, 2003) (summary of the abstract, May 17, 2003) (meeting program, May 17, 2003)	

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